

REMARKS

Claims 1-19 have been canceled. Applicants reserve the right to file one or more continuation or divisional applications directed to the canceled subject matter. Claims 20-24 have been added. New claims 20-21 finds basis in the specification in paragraph [0040] for example. Claims 22 and 23 find basis in the specification at page 10, paragraph [0026], figure 6, and paragraphs [0040] and [0041], for example. Claim 24 finds basis in the specification at paragraphs [0040]-[0042], for example. The specification has been amended to add the statement regarding color drawings or photographs as required by the Office. No new matter is added.

The rejection of claims 1-5 and 9-19 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is respectfully traversed.

The office states that claims 1 and 9-10 recite the limitation of a transformation "system" which the Office states is not clearly defined in the specification as being limited to a composition of matter and implies method steps, making it unclear as to what elements in addition to the claimed products may be encompassed by the claims. The now pending claims no longer

recite a transformation "system".

The Office then states that claims 1, 10, 12, and 18 are vague and indefinite in that the metes and bounds of the term "promoter region" are unclear. The Office states that the term is not explicitly defined in the specification and it is unclear what are the functional/structural characteristics specified by the term "promoter region". The Office then states that it is unclear if the term encompasses elements that have a minimal sequence identity with a polyubiquitin gene promoter element. New claims 20, 21, and 24 now state a polyubiquitin promoter obtained from *Drosophila melanogaster*. This language is recommended by the Office on page 7 of the Official Office action.

The office then states that claims 10 and 18 are also vague and indefinite in that it is unclear as the claim is written whether the "promoter region of a polyubiquitin gene" is necessarily present in the vector or not since the claim structure implies that the promoter region may be part of what was deleted from the vector. The Office then states that this is exacerbated in claim 10 which is directed to a "system" where, if the "promoter region" is actually present, it is unclear if it is merely present in the system or must actually be part of the

vector. The pending claims no longer recite language as found in now canceled claims 10 and 18.

The Office then states that claims 2, 11, 13, and 19 comprise the phrase "a piggyBac transposase helper plasmid under heat-shock promoter regulation". The Office states that first it is unclear that the transposase helper plasmid necessarily comprises a coding sequence for the piggyBac transposase and secondly the phrase implies that it is the entire plasmid comprising a transposase gene that is somehow regulated by the heat-shock protein. New claims 24 now recites a piggyBac transposase that is under control of a heat-shock inducible promoter.

Finally, the Office states that claims 11, 13, and 19 are further indefinite in that they are directed to a vector that "further comprises" a plasmid and states that it is unclear how a vector can further comprise a plasmid. The Office states that upon reading the specification, it appears the phrase may be intended to specify that the transposable element and sequences encoding the corresponding transposase be on the same nucleic acid molecule. New claim 24 now states a composition comprising a first DNA and a second DNA where the second DNA encoding a piggyBac transposase is under control of a heat shock-inducible

promoter.

Withdrawal of the instant rejection is respectfully requested based on the above remarks and amendment to the claims which were made to overcome any vague and indefinite language as pointed out by the Office.

The rejection of claims 1-5, and 9-19, as it now pertains to new claims 20-24, under 35 USC 102 (e) as being anticipated by U.S. Patent No. 6,218,185 ('185). The Office states that the applied reference has a common assignee with the instant application and that based upon the earlier U.S. filing date of the reference, it constitutes prior art under 35 USC 102(e). The Office then states that that this rejection under 35 USC 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention of another or by an appropriate showing under 37 CFR 1.131. The Office further states that the '185 patent teaches a transformation system comprising two DNAs where the first DNA comprises a non-transposon heterologous DNA sequence inserted between the inverted repeats of a piggyBac transposon and the second DNA encodes a transposase active on the pair of inverted repeats (e.g. a transposase helper plasmid). The Office then

states that the first DNA of the invention thus encompasses embodiments where at least 748 basepairs are deleted from the piggyBac transposon and that the nontransposon sequence can be a selectable marker gene encoding a fluorescent protein that is operatively linked to a promoter citing column 8, lines 23-40 and claim 24 as evidence. The Office states that the second DNA can comprise an inducible heat-shock promoter operably linked to the gene encoding the piggyBac transposase such that the transposase helper plasmid is under heat-shock promoter regulation and thus the transformation system taught by the '185 patent anticipates the broadly recited elements of the rejected claims. The Office then states that a more precisely defined wording with regard to the polyubiquitin promoter would probably obviate the instant grounds of rejection for at least some of the claims over the teachings of the '185 patent as the patent does not appear to describe such promoter elements.

The pending claims of the present application now state that the vector comprises at least one sequence encoding a fluorescent protein operatively linked to a polyubiquitin promoter obtained from *Drosophila melanogaster*. The '185 patent fails to teach the use of a fluorescent protein operatively linked to a polyubiquitin promoter obtained from *Drosophila melanogaster*.

The '185 patent only teaches the use of promoters for the control of expression of the targeted sequence, not the transposase sequence. Withdrawal of the instant rejection is respectfully requested.

The rejection of claims 1-5 and 9-19, as it now pertains to new claims 20-24, under 35 USC 102(a) as being anticipated by Handler et al. (Insect Molecular Biology, Vol. 8, No. 4, pages 449-457, November 1999) is respectfully traversed. The Office states that Handler et al. teach the germ line transformation of *D. melanogaster* using a vector marked with white and green fluorescent protein under nuclear-nuclear localizing sequence regulation yielded seventy G1 transformants that all expressed GFP cited Figure 3a and the abstract as evidence. The Office then states that the use of an hsp70-regulated helper construct expressing piggyBac transposase increased transformation frequency significantly and that the authors teach at least one gene transfer construct where 748 bp of piggyBac DNA was deleted from the vector backbone citing column 1 of page 451.

Handler et al., November 1999, is not available prior art for any purpose under 35 USC 102. To support this, Applicant submits herewith an executed Declaration under 37 C.F.R. 1.132 of Dr. Alfred M. Handler. Dr. Handler is one of the co-authors of

Handler et al. and the named inventor of the present application, and named inventor of U.S. Provisional Application 60/225,827 to which the present application claims priority. The Declaration establishes that the disclosure of Handler et al. that relates to the claimed subject matter in the above referenced claims is a publication of the invention of Dr. Alfred M. Handler. This Declaration further establishes that co-author R.A. Harrell, II did not contribute to the conception of the invention, i.e. the claims directed to the claimed subject matter in new claims 20-24.

Since the Declaration establishes that the claimed subject matter in claims 20-24 is the invention of Dr. Alfred M. Handler, the disclosure of Handler et al, with respect to the subject matter of claims 20-24 is not a publication by others and therefore is not prior art under 35 USC 102. Since Handler et al. (published November 1999) is a publication by the inventor within one year of the effective filing date of the claims (the present application claims priority to the 60/225,827 filed August 17, 2000, Handler et al. is not available as prior art for any purpose under 35 USC 102 (or 35 USC 103) for the claimed subject matter of claims 20-24. See In re Katz, 214, USPQ 14 (CCPA 1982); Ex parte Lemieux, 115 USPQ 148 (USPTO Bd. App.,

1957).

Applicants assert that the Declaration under 37 CFR 1.132 of Dr. Alfred M. Handler obviates the objections and rejections under 35 USC 102 (a). Accordingly, withdrawal of the instant rejection is respectfully requested.

The provisional rejection of claims 1-5 and 9-19, as it now applies to new claims 20-24, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-17 of copending Application No. 10/101,840 is respectfully traversed. The Office states that the claims of the '840 application are directed to a transformation system comprising a vector having the identifying characteristics of a vector comprising SEQ ID NO 6 wherein the vector contains a piggyBac transposon digested with BglII-HpaI, a promoter region of a polyubiquitin gene and a nuclear localization sequence of an SV40 virus and can further comprise a selectable marker gene (e.g. encoding a fluorescent marker) operatively linked to the polyubiquitin promoter region. The Office states that the transformation system can further comprise a piggyBac transposase helper plasmid under control of a heat-shock promoter regulation. The Office then states that the claims of the instant specification are broader in scope in that the transformation

system and/or vector of the system comprises a nucleotide sequence from a piggyBac transposon that has a fluorescent protein gene operatively linked to a polyubiquitin promoter region and alternatively the vector can comprise a piggyBac transposon that is modified by deletion of about 748 basepairs of an internal piggyBac sequence. The Office states that in either case, the more narrowly drawn embodiments of the '840 claims are totally encompassed by the instant claims and that the claims of the '840 patent necessarily make obvious the instant claims.

Applicants request that the provisional rejection be held in abeyance. Upon indication of allowable subject matter, Applicants will timely file a terminal disclaimer.

The rejection of claims 1-5 and 9-19, as it now pertains to new claims 20-24, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,11, and 20-26 of U.S. Patent No. 6,218,185 is respectfully traversed. The Office states that the claims of the '185 patent are directed to a transformation system comprising a first DNA comprising a non-transposon and a second DNA encoding transposase active on the pair of inverted repeats where the second DNA is incapable of transposition caused by the transposon. A cell comprising the DNAs of the transformation

system can have the second DNA comprising an inducible heat-shock promoter and the heterologous non-transposon sequence of the first DNA can comprise a selectable marker gene such as a fluorescent protein. The Office then states that the claims of the instant application are directed to a transformation system containing a vector comprising a piggyBac transposon that has been modified by deletion of "about" 748 basepairs of an internal piggyBac sequence and the vector can further comprise a promoter region of a polyubiquitin gene. It then states that the system can further comprise a piggyBac transposase helper plasmid under control of a heat-shock promoter. The Office then states that the concepts of a deletion of about 748 basepairs and a promoter region of a polyubiquitin gene are not explicitly defined in the specification and can be interpreted to read on any deletion of a piggyBac transposon and to any promoter having homology to the polyubiquitin gene promoter. The Office concludes that the claims of the '185 anticipate and make obvious the claims of the instant invention.

Applicants respectfully submit that new claims 20-24 are neither anticipated or obvious over the claims of the '185 patent. First, the present specification clearly defined the deletion of the about 748 basepairs-see for example Figures 6a-f

and Example 1. The claims now recite that the modification is by BglII-HpaI digestion. Furthermore, the claims now recite "a fluorescent protein is operatively linked to a polyubiquitin promoter obtained from *Drosophila melanogaster*" which the Office states that the '185 patent does not appear to describe and that this language would obviate the 102(b) rejection (see page 7 of the Office action with a mail date of May 6, 2004. Therefore, the '185 patent neither anticipates or renders obvious the instantly claimed invention. Withdrawal of the instant rejection is respectfully requested.

It is believed that all of the claims are in condition for allowance. Accordingly, it is respectfully requested that the instant application be allowed to issue. If any issues remain to be resolved, the Examiner is invited to telephone the undersigned at the number below.

In the event this paper is deemed not timely filed, the undersigned hereby petitions for an appropriate extension of time. Please charge any fees, which may be required by this paper or at any time during prosecution of the instant application, or credit any overpayment, to deposit account 50-2134.

Respectfully submitted,

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CERTIFICATE OF FILING VIA FACSIMILE

The undersigned hereby certifies that the attached **AMENDMENT, DECLARATION, AND PETITION FOR A ONE (1) MONTH EXTENTION OF TIME** was this day, August 16, 2004, filed in the United States Patent and Trademark Office via facsimile to facsimile number 703-872-9306. Total pages: 22

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